

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 22, 2010.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010-9512 Filed 4-22-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2009-E-0175 and FDA-2009-E-0173]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; VIMPAT—NDA 22-254

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for VIMPAT based on new drug application (NDA) 22-254 for VIMPAT injection and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim the human drug product, VIMPAT. The regulatory review period determination for VIMPAT Tablets is publishing in this issue of the *Federal Register*.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 0993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-

417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product VIMPAT (lacosamide). VIMPAT injection is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for VIMPAT (U.S. Patent Nos. 5,654,301 and RE38,551) from Research Corporation Technologies, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VIMPAT represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VIMPAT is 3,452 days. Of this time,

3,055 days occurred during the testing phase of the regulatory review period, while, 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* May 19, 1999. The applicant claims November 14, 2003, as the date an investigational new drug application (IND) became effective. However, according to FDA records, this IND was not the first IND received for this active ingredient. In general, FDA has used the first IND of the active ingredient of the drug product as the beginning of the testing phase, if information derived from this first IND was or could have been relied on or was relevant for approval to market the drug product. FDA records indicate that the effective date of the first IND for lacosamide was May 19, 1999, which was 30 days after FDA receipt of this first IND. This is the same IND and the same date FDA determined was the beginning of the regulatory review period for Vimpat Tablets approved under new drug application (NDA) 22-253. The regulatory review period determination for VIMPAT Tablets is publishing in this issue of the *Federal Register*.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* September 28, 2007. FDA has verified the applicant's claim that the new drug application (NDA) 22-254 for VIMPAT injection was submitted on September 28, 2007.

3. *The date the application was approved:* October 28, 2008. FDA has verified the applicant's claim that NDA 22-254 was approved on October 28, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,104 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and ask for a redetermination by June 22, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 20, 2010. To meet its burden,

the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

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Dated: March 22, 2010.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010-0509 Filed 4-22-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0159]

#### North American Bioproducts Corp.; Filing of Food Additive Petition (Animal Use); Erythromycin Thiocyanate

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that North American Bioproducts Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of erythromycin thiocyanate as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in by-product distiller grains used as an animal feed or feed ingredient.

**DATES:** Submit written or electronic comments on the petitioner's environmental assessment May 24, 2010.

**ADDRESSES:** You may submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl.,

Rockville, MD 20855, 240-453-6853, email: [isabel.pocurull@fda.hhs.gov](mailto:isabel.pocurull@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2263) has been filed by North American Bioproducts Corp., Corporate Support Center, 1815 Satellite Blvd., Building 200, Duluth, GA 30097. The petition proposes to amend the food additive regulations in 21 CFR Part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of erythromycin thiocyanate as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in by-product distiller grains used as an animal feed or feed ingredient.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see ADDRESSES) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the *Federal Register*. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the *Federal Register* in accordance with 21 CFR 25.51(b).

Dated: April 14, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010-0420 Filed 4-22-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Fiscal Year (FY) 2010 Funding Opportunity

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of intent to award a Single Source Grant to the current grantee for the National Center for Child Traumatic Stress.

**SUMMARY:** This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately \$1,000,000 (total costs) for up to one year to the current grantee for the National Center for Child Traumatic Stress (NCCTS). This is not a formal request for applications. Assistance will be provided only to the current grantee for the National Center for Child Traumatic Stress based on the receipt of a satisfactory application that is approved by an independent review group.

*Funding Opportunity Title:* SM-10-016.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.243.

*Authority:* Section 582 of the Public Health Service Act, as amended.

*Justification:* Only an application from the current grantee for the National Center for Child Traumatic Stress will be considered for funding under this announcement. One-year funding has become available to assist SAMHSA in responding to data analysis and reporting activities that improve evidence-based practices and raise the standard of trauma care. It is considered most cost-effective and efficient to supplement the existing grantee because they have access to the existing National Child Traumatic Stress Network (NCTSN) datasets and data analytic expertise to conduct the required data analytic activities. There is no other potential organization with the required access and expertise.

Eligibility for this program supplement is restricted to the current grantee, National Center for Child Traumatic Stress in accordance with Congressional intent for 2010 SAMHSA appropriations.

The role of the NCCTS is to provide infrastructure and support for the National Child Traumatic Stress Network to achieve its goals of increasing access and raising the standard of care for traumatized children, adolescents, and their